REMARKS

Claims 1-14, 16, 17, and 20-28 are pending in this application. Claims 1, 7, 8, 10, 11, 16, 17, and 20 have been amended. Claims 15, 18, and 19 have been canceled. New claims 21-28 have been added. Support for the amendments and new claims is found in the specification and claims as filed.

Objection to the Specification

The specification has been objected to for typographical errors appearing in the abstract and at page 1, line 10 of the specification, and for an incorrect brief description of Fig. 3A. Appropriate correction has been made. Accordingly, Applicant respectfully requests that the objection be withdrawn.

Claim Rejections - 35 U.S.C. § 112, second paragraph

Claim 10 has been rejected under 35 U.S.C. §112, second paragraph. Claim 1 has been amended to recite "a cyanoacrylate wound-sealing adhesive", thereby providing antecedent basis for the adhesive recited in Claim 10. Accordingly, Applicant respectfully requests withdrawal of the rejection.

Claim Rejections - 35 U.S.C. § 102(b)

Claims 1, 5, 7, 8, and 10 have been rejected under 35 U.S.C. §102(b) as anticipated by U.S. 4,616,642 (hereinafter "Martin et al."). "A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." *See, e.g., In re Paulsen*, 31 U.S.P.Q.2d 1671 (Fed. Cir. 1994). Martin et al. does not disclose every element of Applicant's claims, and therefore cannot be considered as an anticipating reference under 35 U.S.C. § 102(b).

Independent Claim 1 recites "[a] wound approximation device, the device comprising: a cyanoacrylate wound-sealing adhesive; and a solid resilient sheet comprising an opening, wherein the opening is of a sufficient size such that it surrounds a skin wound and exposes a margin of skin surrounding the wound when the resilient sheet in a stretched form is placed against the skin, wherein the resilient sheet is configured to approximate the wound when allowed to relax into an unstretched form when placed against the skin, and wherein a portion of the resilient sheet adjacent to the opening and opposite to a side of the resilient sheet to be placed against the skin comprises a substance which does not form a strong bond with the cured cyanoacrylate wound-sealing adhesive, such when the cyanoacrylate wound-sealing adhesive is

applied through the opening to the margin of skin surrounding the approximated wound so as to seal the wound upon curing, the resilient sheet can be removed from against the skin without disturbing the cured cyanoacrylate adhesive sealing the wound."

Martin et al. disclose a surgical drape for caesarean section. Cyanoacrylate adhesives are not disclosed in Martin et al. for use in conjunction with the drape. The drape includes a "tear-drop" for ovate-rotundate fenestration. The dimensions of the fenestration are given as about 7 to about 10 inches across the widest part of the base and between the most widely separated points, top to bottom, respectively. See col. 3, lines 61-65. Such a fenestration is incapable of approximating a skin wound. The term "approximating" as employed within the medical community is defined as "the act or process of bringing closer together or into apposition." See Dorland's Illustrated Medical Dictionary, Copyright 2002 W. B. Saunders. One skilled in the medical arts understands the phrase "approximating a skin wound" to describe bringing the edges of the skin wound closer together or into apposition. Accordingly, Martin et al. does not disclose an "opening" as claimed.

The fenestration is surrounded on three sides by a region having a second or supplemental absorbent material. See col. 4, lines 24-26. Preferred absorbent materials include wood pulp, cellulose wadding, webs or batrices of a cellulosic material, or such materials in combination with a thermoplastic material such as a polyolefin, or the like. See col. 5, lines 30-38. A cyanoacrylate adhesive would adhere to such materials and to skin, preventing removal of the drape. Accordingly, Martin et al. does not disclose "a portion of the resilient sheet adjacent to the opening and opposite to a side of the resilient sheet to be placed against the skin comprises a substance which does not form a strong bond with the cured cyanoacrylate wound-sealing adhesive"

Accordingly, Applicant respectfully requests that the rejection be withdrawn.

Claim Rejections - 35 U.S.C. § 102(b)

Claims 1, 2, 4, and 6 have been rejected under 35 U.S.C. §102(b) as anticipated by U.S. 3,668,050 (hereinafter "Donnelly"). "A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." *See, e.g., In re Paulsen*, 31 U.S.P.Q.2d 1671 (Fed. Cir. 1994). Donnelly does not disclose every element of Applicant's claims, and therefore cannot be considered as an anticipating reference under 35 U.S.C. § 102(b).

Independent Claim 1 recites "[a] wound approximation device, the device comprising: a cyanoacrylate wound-sealing adhesive; and a solid resilient sheet comprising an opening, wherein the opening is of a sufficient size such that it surrounds a skin wound and exposes a margin of skin surrounding the wound when the resilient sheet in a stretched form is placed against the skin, wherein the resilient sheet is configured to approximate the wound when allowed to relax into an unstretched form when placed against the skin, and wherein a portion of the resilient sheet adjacent to the opening and opposite to a side of the resilient sheet to be placed against the skin comprises a substance which does not form a strong bond with the cured cyanoacrylate wound-sealing adhesive, such when the cyanoacrylate wound-sealing adhesive is applied through the opening to the margin of skin surrounding the approximated wound so as to seal the wound upon curing, the resilient sheet can be removed from against the skin without disturbing the cured cyanoacrylate adhesive sealing the wound."

Donnelly discloses a surgical drape with a fenestration area. Cyanoacrylate adhesives are not disclosed in Martin et al. for use in conjunction with the drape. The drape includes a sheet of fluid absorbent flexible plastic foam material laminated to the outer layer of the fluid impervious film atop the fibrous base sheet. The fenestration area extends through all three layers of the material. A cyanoacrylate adhesive would be absorbed by and bonded to the fluid absorbent material, even if the material comprises a low surface energy material, as well as to skin, preventing removal of the drape. A cyanoacrylate would also bond to the fibrous base sheet, preventing removal of the drape. Accordingly, Donnelly does not disclose "a portion of the resilient sheet adjacent to the opening and opposite to a side of the resilient sheet to be placed against the skin comprises a substance which does not form a strong bond with the cured cyanoacrylate wound-sealing adhesive"

Accordingly, Applicant respectfully requests that the rejection be withdrawn.

Claim Rejections - 35 U.S.C. § 102(b)

Claim 11 has been rejected under 35 U.S.C. §102(b) as anticipated by EP 28452 A1 (hereinafter "Sanderson"). "A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." *See, e.g., In re Paulsen*, 31 U.S.P.Q.2d 1671 (Fed. Cir. 1994). Sanderson does not disclose every element of Applicant's claims, and therefore cannot be considered as an anticipating reference under 35 U.S.C. § 102(b).

Independent Claim 11 recites "[a] method of sealing a wound, the method comprising the steps of: providing a wound approximation device, the device comprising a solid resilient sheet comprising an opening, wherein a portion of the resilient sheet adjacent to the opening and opposite to a side of the resilient sheet to be placed against the skin comprises a substance which does not form a strong bond with a cured cyanoacrylate adhesive; applying tension to the resilient sheet whereby the opening is enlarged to a sufficient size such that it can surround a skin wound and expose a margin of skin surrounding the wound; pressing the resilient sheet under tension against the skin to form a bond to the skin, such that the opening surrounds the skin wound and exposes a margin of skin surrounding the wound; releasing the tension in the resilient sheet, whereby the wound is approximated; applying a cyanoacrylate adhesive through the opening to the margin of skin surrounding the approximated wound; allowing the cyanoacrylate adhesive to cure, whereby the wound is sealed; and removing the resilient sheet from against the skin without disturbing the cured cyanoacrylate adhesive sealing the wound."

Sanderson discloses an adhesive skin closure. Cyanoacrylate adhesives are not disclosed in Sanderson for use in conjunction with the closure. Accordingly, Sanderson does not disclose "applying a cyanoacrylate adhesive". The closure of Sanderson is described as "air permeable and moisture vapour permeable." See page 9, lines 14-15. Accordingly, Sanderson does not disclose a "providing a wound approximation device ... comprising a solid resilient sheet." The closure is described as holding the edges of a laceration together during the healing process, rather than during a wound sealing using a cyanoacrylate adhesive. See page 9, lines 10-13. Accordingly, Sanderson does not disclose removing the resilient sheet from against the skin without disturbing the cured cyanoacrylate adhesive sealing the wound."

Accordingly, Applicant respectfully requests that the rejection be withdrawn.

Claim Rejection - 35 U.S.C. § 103(a)

Claim 9 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Martin et al. in view of U.S. 3,971,766 (hereinafter "Ono et al."). To articulate a *prima facie* case of obviousness, the PTO must, *inter alia*, cite prior art that teaches or suggests all the claimed limitations. *In re Royka*, 490 F.2d 981 (C.C.P.A. 1974).

Ono et al. includes no disclosure that remedies the deficiencies of Martin et al. Ono et al. merely discloses specified pressure sensitive alkylacrylate adhesives (not *cyano*acrylate adhesives) suitable for use for use on adhesive tape or drape.

Because the cited art, alone or in combination, fails to teach or suggest all of the claimed limitations, a *prima facie* case of obviousness against Claim 9 cannot be made. Accordingly, Applicant respectfully requests withdrawal of the pending rejection.

Claim Rejection - 35 U.S.C. § 103(a)

Claims 11-15, 18, and 19 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. 6,410,818 (hereinafter "Oyaski") in view of Sanderson. Claims 15, 18, and 19 have been canceled, without prejudice, solely to facilitate prosecution of the remaining claims. Applicant reserves the ability to pursue the canceled claims or similar claims, in one or more continuing applications.

To articulate a *prima facie* case of obviousness, the PTO must, *inter alia*, cite prior art that teaches or suggests all the claimed limitations. *In re Royka*, 490 F.2d 981 (C.C.P.A. 1974). Oyaski includes no disclosure that remedies the deficiencies of Sanderson. Oyaski merely discloses a device for drawing a stress crack together, wherein a medical adhesive is applied to the crack through an aperture in the device covered by a screen member. After the adhesive dries, the device is removed, leaving the adhesive and screen member attached to the skin. Oyaski does not disclose any particular material from which the device can be constructed or any particular medical adhesive suitable for use with the device, much less cyanoacrylate adhesives as are presently claimed. Oyaski does not disclose that the medical adhesive can be in contact with any portion of the device that is removed from the body. Moreover, there is no teaching or suggestion regarding compatibility (or lack thereof) of any material in the removable portion of the device and the adhesive.

Because the cited art, alone or in combination, fails to teach or suggest all of the claimed limitations, a *prima facie* case of obviousness against the claims cannot be made. Accordingly, Applicant respectfully requests withdrawal of the pending rejection against Claims 11-14.

Claim Rejection - 35 U.S.C. § 103(a)

Claims 16 and 17 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Sanderson in view of Oyaski. To articulate a *prima facie* case of obviousness, the PTO must, *inter alia*, cite prior art that teaches or suggests all the claimed limitations. *In re Royka*, 490 F.2d 981 (C.C.P.A. 1974).

As discussed above, Oyaski includes no disclosure that remedies the deficiencies of Sanderson. Accordingly, because the cited art, alone or in combination, fails to teach or suggest

all of the claimed limitations, a *prima facie* case of obviousness against the claims cannot be made.

Further Comments Regarding Rejection Under 35 U.S.C. § 103(a) Over Oyaski in view of Sanderson

It is noted that certain of the cited references disclose cyanoacrylate adhesives. Even if such references were combined with Oyaski and Sanderson, or any of the other cited references, a *prima facie* case of obviousness could not be made. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Such teaching, suggestion, or motivation is absent, and thus a *prima facie* case of obviousness cannot be made. Even if a *prima facie* case of obviousness could be made, it may be rebutted by showing that the art, in any material respect, teaches away from the claimed invention. *In re Geisler*, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997).

Submitted herewith is the product insert for DERMABOND® topical skin adhesive (2-octyl cyanoacrylate) manufactured by Closure Medical Corp. DERMABOND® is described as "a fast setting adhesive capable of adhering to most body tissue and many other materials, such as latex gloves and stainless steel. Inadvertent contact with any body tissue, and any surfaces or equipment that are not disposable or that cannot be readily cleaned with a solvent such as acetone should be avoided." See page 2 of product insert. Regarding application of DERMABOND®, it is recommended to "[a]pproximate wound edges with gloved fingers or sterile forceps", apply DERMABOND®, and to "maintain manual approximation of the wound edges" after application of DERMABOND®. See page 6 of product insert. Moreover, "[i]f a dressing, bandage, adhesive backing or tape is applied before complete polymerization, the dressing can adhere to the film. The film can be disrupted from the skin when the dressing is removed, and wound dehiscence can occur." See page 7 of product insert.

As taught by the product insert, one skilled in the art of wound closure with cyanoacrylate adhesives would attempt to avoid any incidental contact between a cyanoacrylate medical adhesive and a substance (e.g., latex gloves, stainless steel forceps, dressing, bandage, adhesive backing, tape, or the like) other than the skin to be bonded. There would be no motivation to

deliberately initiate, or to permit, contact between a wound approximation device and a cyanoacrylate adhesive because of the risk of wound dehiscence when attempting to remove a device strongly bonded to the body by the cyanoacrylate adhesive. Even if one were motivated to deliberately initiate, or to permit, contact between a wound approximation device and a cyanoacrylate adhesive, there is no teaching or suggestion in the cited references of how to do so without disturbing the cured cyanoacrylate adhesive sealing the wound.

Applicant has unexpectedly and surprisingly discovered that a wound approximation device can be fabricated that is suitable for use in sealing wounds using cyanoacrylate adhesives, and that avoids the problem of wound dehiscence upon removal of the device from the wound after incidental contact of the device to the cyanoacrylate adhesive. Accordingly, Applicant respectfully requests withdrawal of the pending rejection.

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 27, 2004

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